Remarks

I. Claim rejections under 35 U.S.C.§ 112, second paragraph

The Office Action rejects claims 1-22 under 35 U.S.C.§ 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention.

In particular, the Office Action asserts that 1) it is uncertain that the term "equivalent" in claim 1 is intended to mean a tissue equivalent or not; 2) it is unclear that the term "the tissue" refers to subject's tissue or the "equivalent" tissue; 3) the term "further comprises" in claim 11 should be replaced by the term "comprises"; 4) it is unclear whether the composition in claims 16 and 19 comprises three tissue segments; and 5) it is unclear whether the claims 20-22 are directed to a processed histological/TUNEL sample or an intended use of the sample.

To the extent the rejection can be applied to the amended claims, Applicant respectfully traverses.

First, Applicant has amended claim 1 to substitute the term "equivalent" with the term "naturally occurring", which is supported by the specification (See, p. 6, l. 21).

Second, Applicant has amended claim 2-22 to include the term "the segment" which is directed to the "segment of a naturally occurring tissue" of claim 1.

Third, Applicant has removed the term "further" in claim 11.

Fourth, Applicant has amended claims 16 and 19 to "further" comprise at least two additional segments: a negative control segment and a positive control segment.

Finally, Applicant has amended claims 20-22 to be directed to a further intended step of processing.

In light of the foregoing, Applicant has made amendments in accordance with the suggestions made by the Office Action and therefore made the rejections under 35 U.S.C.§ 112, second paragraph, moot. Accordingly, Applicant respectfully requests that the rejections be reconsidered and withdrawn.

II. Claim rejections under 35 U.S.C.§102.

The Office Action rejects claims 1-15, 17-22 under §102(b) as being anticipated by Doolin et al. (59 J. Surg. Res. 191-197 (1995); 20 J. Burn Car & Rehab. 364-376 (1999); 5 Tissue Engineering 573-581 (1999)). The Office Action asserts that the tissue cited in prior art would have all of the claimed characteristics and that an intended use of a composition and how those inherent characteristics are measured or induced are of little patentable weight. To the extent the rejections can be applied to the amended claims, Applicant respectfully traverses.

To anticipate a claim, a prior art reference must teach every element of the claim. Applicant notes that Doolin et al. in 20 J. Burn Car & Rehab. 364-376 (1999) and 5 Tissue Engineering 573-581 (1999) teach bioartifical living skin equivalents or cultured skin constructs. Applicant further notes that bioartificially constructed tissues are not naturally occurring tissues and are merely "equivalent to naturally occurring tissue" (p. 6, l. 21). It is reminded that the claimed invention is directed to a "naturally occurring tissue."

Doolin et al. in 59 J. Surg. Res. 191-197 (1995) teach a hypoplastic lung tissue which results from pulmonary hypoplasia. However, the hypoplastic lung tissue taught by Doolin et al. has not been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis and therefore is not the naturally occurring tissue of the claimed invention.

In light of the foregoing, Applicant believes none of the prior references teach every element of the claimed invention. Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C.§102 (b) be reconsidered and withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in the instant application is believed to be in immediate condition for allowance. Accordingly, a Notice of Allowance is respectfully requested.

Respectfully submitted,
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